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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,623	03/10/2004	Edward I. Wulfman	89000.3013NP	6167

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EXAMINER

HORNBERGER, JENNIFER LEA

ART UNIT	PAPER NUMBER
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3734

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06/09/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/798,623	Applicant(s) WULFMAN ET AL.	
	Examiner JENNIFER L. HORNBERGER	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-5, 10 and 16-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-5, 10 and 16-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/23/2009 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 2/18, 3/18, 4/18, 16/18, 17/18, and 26/18 are rejected under 35 U.S.C. 102(b) as being anticipated by Zacca et al. (US 5,217,474).

Regarding claims 18 and 26, Zacca et al. disclose an intracorporeal medical device having a rotatable torque tube (8) and a sealing assembly (14) for creating a liquid seal around the torque tube during operation of the device, the sealing assembly comprising a housing (10) enclosing at least a portion of the torque tube in a manner that permits free rotation and axial translation of the torque tube, the housing including an infusion port (3) providing a sealing liquid; and a liner (14) surrounding the rotatable torque tube in the area of the infusion port and extending longitudinally less than the axial length of the torque tube in a distal direction from the infusion port (Fig. 1), the liner forming a flood space between the inner surface of the liner and

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the torque tube (8) whereby the sealing liquid enters the flood space (34; col. 6, ln. 32-34) and prevents air from entering the space external to the torque tube during operation of the device.

Regarding claim 2, Zacca et al. disclose the flood space (34) includes a clearance area between the liner and the torque tube.

Regarding claim 3, Zacca et al. disclose the torque tube is a coiled drive shaft (8) and the flood space includes gaps between the coils.

Regarding claim 4, Zacca et al. disclose the torque tube (8) includes a lumen (64) for a guidewire and the flood space includes the lumen.

Regarding claim 16, Zacca et al. disclose a drive system (1) coupled to the torque tube to rotate the torque tube.

Regarding claim 17, Zacca et al. disclose a hand held unit (10) and the sealing assembly housed within the hand held unit.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 2/19-5/19, 2/20-5/20, 10, 16/19, 16/20, 17/19, 17/20, 19, 20, 22/19, 22/20, 23/19, 23/20, 26/19, and 26/20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zacca et al. (US 5,217,474) in view of Mische et al. (US 5,490,859).

Regarding claims 19 and 26, Zacca et al. disclose a device having a liquid seal assembly for creating a liquid seal in a medical device, the medical device comprising: a torque tube (8) operably connected to a drive system (1) for rotation; a liner (14) surrounding the rotatable torque tube to form a liquid flood space (34) en the liner and the torque tube, the liner

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extending longitudinally less than the axial length of the torque tube and terminating at an intersect area (Fig. 1). Zacca et al. disclose an additional catheter or a guide catheter enclosing the torque tube (col. 7, ln. 51-58), but fail to disclose guide tube is an aspiration catheter enclosing the torque tube and the liner and extending distally beyond the intersect area with respect to the operator, the catheter forming an aspiration lumen between the catheter and the liner; whereby liquid drawn into the flood space during operation of the catheter system exits the flood space at the intersect area and enters the aspiration lumen. Mische et al. disclose an aspiration catheter (or guide catheter) enclosing a torque tube (92) having a liner (90; col. 25, ln. 61 – col. 26, ln. 4). Mische et al. further discloses that fluid is provided through the drive shaft and or through the liner (90) to generate positive pressure within the vascular lumen while negative pressure is provided through the guide catheter in order to cause a pressure differential within the lumen to force fluid and occlusion particulate proximally through the guide catheter. It would have been obvious to one of ordinary skill in the art to provide negative pressure to the guide catheter of Zacca et al. in order to create a pressure difference and to pull the fluid and occlusion particulate proximally to remove the particulate from the body as suggested by Mische et al.

Regarding claims 20 and 26, Zacca et al. disclose a medical device comprising: a rotatable torque tube (8) operably connected to a drive system (1) for rotation and a liner (14) surrounding the torque tube (8) and forming a flood space (34) extending from a sealing assembly along at least a portion of the torque tube to an intersect area (Fig. 1); the sealing assembly in communication with an infusion port (3) providing application of liquid to the flood space during operation of the device. Zacca et al. disclose an additional catheter or a guide catheter enclosing the torque tube (8; col. 7, ln. 51-58) and the catheter enclosing the intersect area of the liner, but fail to disclose an aspiration between the catheter and the liner. Mische et

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al. disclose an aspiration catheter (or guide catheter) enclosing a torque tube (92) having a liner (90; col. 25, ln. 61 – col. 26, ln. 4). Mische et al. further discloses that fluid is provided through the drive shaft (92) and/or through the liner (90) to generate positive pressure within the vascular lumen while negative pressure is provided through the guide catheter in order to cause a pressure differential within the lumen to force fluid and occlusion particulate proximally through the guide catheter. It would have been obvious to one of ordinary skill in the art to provide negative pressure to the guide catheter of Zacca et al. in order to create a pressure difference and to pull the fluid and occlusion particulate proximally to remove the particulate from the body as suggested by Mische et al.

Regarding claim 2, Zacca et al. disclose the flood space (34) includes a clearance area between the liner and the torque tube.

Regarding claim 3, Zacca et al. disclose the torque tube is a coiled drive shaft (8) and the flood space includes gaps between the coils.

Regarding claim 4, Zacca et al. disclose the torque tube (8) includes a lumen (64) for a guidewire and the flood space includes the lumen.

Regarding claim 5, Zacca et al. in view of Mische et al. disclose a suction port for aspirating fluid from a lumen and wherein the pressure in the flood space is lower than the pressure outside or proximal to the flood space during operation of the device (col. 25, ln. 61 – col. 26, ln. 4).

Regarding claim 10, Zacca et al. disclose the sealing member further comprises an overflow port for exit of excess liquid and wherein the torque tube extends through the overflow port.

Regarding claim 16, Zacca et al. disclose a drive system (1) coupled to the torque tube to rotate the torque tube.

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Regarding claim 17, Zacca et al. disclose a hand held unit (10) and the sealing assembly housed within the hand held unit.

Regarding claim 22, Zacca et al. discloses drive shaft coil with a diameter as small as .032 inches (col. 6, ln. 2), but fail to disclose the inner diameter of the liner. It would have been obvious to one having ordinary skill in the art at the time the invention was made to optimize the diameter of the liner to at least accommodate the drive shaft coil, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claim 23, Zacca et al. disclose the claimed invention except for the liner length being more than about 6 inches. It would have been obvious to one having ordinary skill in the art at the time the invention was made to optimize the length of the liner, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the

6. Claims 21/18 and 27/18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zacca et al. (US 5,217,474) in view of Keith et al. (US 5,938,670). Zacca et al. fail to disclose that the pressure within the flood space decreases along the length of the liner in a distal direction during operation of the device and that the length and diameter of the liner forming the flood space are selected to reduce the rate of flow in the proximal to distal direction in the flood space and reduce the requirement for precise diametrical tolerances during operation of the device. Keith et al. disclose that a smaller gap provides more resistance to fluid flow and therefore reduces pressure within a flood space along the length of a liner in a distal direction during the operation of the device in order to prevent significant fluid loss and provide effective cooling of a drive shaft. (col. 12, ln. 11-34). It would have been obvious to one of ordinary skill in the art to dimension the diameter and the length of the liner of Zacca et al. to provide more resistance to fluid flow, thereby reduce pressure within the flood space and reduce the rate of

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fluid flow along the length of the liner as taught by Keith et al. to provide more effective cooling of the drive shaft coil.

7. Claims 21/19, 21/20, 27/19, and 27/20 are rejected under 35 U.S.C. 103(a) as being unpatentable over or over Zacca et al. (US 5,217,474) in view of Mische et al. (US 5,490,859) as applied to claims 19 or 20 above, and further in view of Keith et al. (US 5,938,670). Zacca et al. fail to disclose that the pressure within the flood space decreases along the length of the liner in a distal direction during operation of the device and that the length and diameter of the liner forming the flood space are selected to reduce the rate of flow in the proximal to distal direction in the flood space and reduce the requirement for precise diametrical tolerances during operation of the device. Keith et al. disclose that a smaller gap provides more resistance to fluid flow and therefore reduces pressure within a flood space along the length of a liner in a distal direction during the operation of the device in order to prevent significant fluid loss and provide effective cooling of a drive shaft. (col. 12, ln. 11-34). It would have been obvious to one of ordinary skill in the art to dimension the diameter and the length of the liner of Zacca et al. to provide more resistance to fluid flow, thereby reduce pressure within the flood space and reduce the rate of fluid flow along the length of the liner as taught by Keith et al. to provide more effective cooling of the drive shaft coil.

8. Claims 22/18 and 23/18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zacca et al. (US 5,217,474).

Regarding claim 22, Zacca et al. discloses drive shaft coil with a diameter as small as .032 inches (col. 6, ln. 2), but fail to disclose the inner diameter of the liner. It would have been obvious to one having ordinary skill in the art at the time the invention was made to optimize the diameter of the liner to at least accommodate the drive shaft coil, since it has been held that

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where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claim 23, Zacca et al. disclose the claimed invention except for the liner length being more than about 6 inches. It would have been obvious to one having ordinary skill in the art at the time the invention was made to optimize the length of the liner, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

9. Claims 24/18 and 25/18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zacca et al. (US 5,217,474) in view of Milo (US 6,258,052) and Machold et al. (US 4,976,720). Zacca et al. is silent as to the material of the liner (14). Milo discloses a polyimide tube in contact with a coiled wire or shaft increases pushability and column strength (col. 2, ln. 61 - col. 3, ln. 2). It would have been obvious to one of ordinary skill to have tried making the liner of polyimide tubing to provide the same advantages to the coiled torque tube of Keith et al. to prevent buckling during vascular occlusion ablation. Keith et al. in view of Milo fail to disclose a lubricious coating. Machold et al. disclose a polyimide tube having a lubricious coating (col. 5, ln. 3-4). It would have been obvious to one of ordinary skill in the art provide a lubricious coating on the polyimide liner to reduce friction between the drive shaft and the liner.

Claims 24/19, 24/20, 25/19, and 25/20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zacca et al. (US 5,217,474) in view of Mische et al. (US 5,490,859) as applied to claims 19 or 20 above, and further in view of Milo (US 6,258,052) and Machold et al. (US 4,976,720). Zacca et al. is silent as to the material of the liner (14). Milo discloses a polyimide tube in contact with a coiled wire or shaft increases pushability and column strength (col. 2, ln. 61 - col. 3, ln. 2). It would have been obvious to one of ordinary skill to have tried making the liner of polyimide tubing to provide the same advantages to the coiled torque tube of

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Keith et al. to prevent buckling during vascular occlusion ablation. Keith et al. in view of Milo fail to disclose a lubricious coating. Machold et al. disclose a polyimide tube having a lubricious coating (col. 5, ln. 3-4). It would have been obvious to one of ordinary skill in the art provide a lubricious coating on the polyimide liner to reduce friction between the drive shaft and the liner.

Response to Arguments

10. Applicant's arguments with respect to claims 2-5, 10, and 16-27 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER L. HORNBERGER whose telephone number is (571)270-3642. The examiner can normally be reached on Monday through Friday from 8am-5pm, Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571)272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3734